Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Oka S. The effects of Oren-to on stomatitis. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine*) 1995; 46: 439–45 (in Japanese with English abstract). CiNii

1. Objectives

To evaluate the efficacy and safety of orento (黄連湯) in the treatment of stomatitis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Thirty patients with stomatitis.

5. Intervention

Arm 1: TAIKODO Orento (黄連湯) Extract at a dose of 4.5 g t.i.d. for acute aphthous stomatitis (n=18).

Arm 2: oral steroid ointment 2–3 applications/day for acute aphthous stomatitis (n=5).

Arm 3: no treatment for acute aphthous stomatitis (n=5).

Arm 4: TAIKODO Orento (黄連湯) Extract at a dose of 4.5 g t.i.d. for chronic stomatitis (n=2).

6. Main outcome measures

Number of days to resolution of pain and cure of stomatitis.

7. Main results

The mean number of days to resolution of pain was 2.1, 7.0, and 17.0 in arms 1, 2, and 3, respectively, showing a significant decrease in arm 1 compared even with arm 2. The mean number of days to a cure of stomatitis was 5.5, 12.0, and 17.0 in arms 1, 2, and 3, respectively, showing that time to cure was also significantly decreased in arm 1 compared even with arm 2. In arm 4, pain recurred after resolution.

8. Conclusions

Orento is effective for acute aphthous stomatitis.

9. From Kampo medicine perspective

Mentioned in the discussion section of the reference.

10. Safety assessment in the article

No adverse reactions were reported.

11. Abstractor's comments

This was a valuable controlled clinical trial showing that orento is effective for acute aphthous stomatitis. Despite an imbalance in the number of patients among the groups, the results definitely showed the efficacy of orento. These results suggested that acute aphthous stomatitis may be a symptom of *jitsu-sho* (実証, excess pattern). Chronic stomatitis may require treatment based on *sho*. A future randomized controlled trial should include a description of the randomization method, statistical analysis of the results, and a larger control group.

12. Abstractor and date

Okabe T, 19 August, 2008, 1 June 2010.